U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
www.samhsa.gov

FREQUENTLY ASKED QUESTIONS ABOUT THE YIW INITIATIVE AND GRANT APPLICATIONS

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BASIC INFORMATION

1. What are the YIW initiative's purpose, goals, and objectives?

The YIW initiative is a multisite collaborative whose purpose is to build a strategic, cooperative alliance among multidisciplinary teams that are interested in studying the effectiveness of workplace-based substance abuse prevention and early intervention programs for young adults (ages 16 to 24). The primary purpose of the collaborative is to study the effectiveness of diverse approaches to prevention and early intervention of substance abuse and thereby provide the nation's (private and public) employers with empirical information about "what works" for employed young adults.

The focus of the collaborative is on young adults because they represent a segment of the population in which the prevalence of substance use is high and is associated with increased risk for developing chronic substance use-related problems; and for which few established interventions are available, particularly in workplaces. Each of the collaborating teams will study one or more existing workplace interventions and will cooperate in a cross-site evaluation of those interventions implemented by the collaborative's Cross-Site Evaluation Contractor.

The primary specific aims of the collaborative are to

- assess the impact of the YIW interventions in preventing and/or reducing substance abuse for youthful employees and their families;
- assess the effectiveness of specific intervention strategies in achieving positive outcomes as defined by individual grantees;
- assess confounding and intervening influences on effectiveness;
- document the process of YIW service delivery and implementation across programs; and
- as feasible, assess the impact of the YIW interventions on related health and social problems, such as violence, teen pregnancy, and HIV/AIDS.

Please see the YIW tools entitled "Annotated Reference List" and "Contextual and Other Factors Related to YIW."

2. What do "YIW" and "YIT" stand for?

"YIW" stands for Youth Transition into the Workplace, and "YIT" stands for Youth in Transition. These two acronyms are used interchangeably to refer to the SAMHSA/CSAP initiative whose formal title is "Workplace Prevention and Early Intervention: Transitioning Youth into the Workplace." As noted above, this initiative was created to facilitate successful integration of young adults (ages 16 to 24) into workplaces by reducing the incidence and prevalence of substance abuse among this population.

3. What is meant by "prevention"?

An Institute of Medicine (IOM) committee (1994) recommended a definition of "prevention" as interventions that take place before the onset of a disorder. IOM classifies preventive interventions into three categories:

- *Universal preventive interventions* target the general public or an entire population not identified on the basis of individual risk.
- *Selective preventive interventions* target populations whose risk of a disorder is significantly higher than average at present or over a lifetime.
- *Indicated preventive interventions* target high-risk individuals who have minimal but detectable signs or symptoms, which may lead to a mental disorder.

4. What is meant by "early intervention"?

"Early intervention" refers to preventive efforts aimed at persons who are

- at high risk prior to their having a serious consequence related to substance use; or
- at high risk and have had limited serious consequences; or
- at high risk and have had a significant personal, economic, legal, or health/mental health consequence

and providing these persons with appropriate counseling, treatment, education, or other intervention.

5. What is meant by "substance abuse"?

"Substance abuse" refers to the abuse of alcohol and/or drugs.

6. What is meant by "drugs"?

"Drugs" refers to illicit drugs.

7. Can YIW substance abuse prevention and early intervention programs include drug testing?

Yes.

8. Why is the YIW funded through the cooperative agreement mechanism?

This is SAMHSA/CSAP's first opportunity to establish an empirical database that documents the experience of employers with interventions aimed at preventing substance abuse among their young adult employees. It is also our first opportunity to examine

broadly the workplace response to substance abuse among youthful employees and their families. The cooperative agreement mechanism was chosen so that grantees will be able to have the active support of program staff and a Cross-Site Evaluation Contractor. In addition to collecting and analyzing individual data, we also constructed an active role for grantees on a Steering Committee so that each will be able to have access to the others and so that all can come to agreement on the collection and analysis of certain common data.

9. What is meant by "private sector" and "public sector"?

Applicants may be organizations from the private sector, such as corporations, industries, consulting firms, universities, and nonprofit or for-profit agencies; or agencies in the public sector, such as state or local governments. The common denominator is that applicants must have access to one or more substance abuse prevention and early intervention programs for youth.

10. What constitutes a workplace/worksite/work environment?

For YIW purposes, the workplace/worksite/work environment is the location where full- or part-time employment is secured.

11. What is meant by "employment"?

"Employment" means work performed for wages under a contract of hire, written or oral, expressed or implied, including service in interstate commerce.

12. Why is SAMHSA/CSAP interested in these youthful workers?

The number of 16- to 24-year-olds in the labor force is expected to increase by 3.4 million by 2010, making the youth labor force larger than it has ever been. As the labor force becomes younger, workplaces will be faced with new problems because youth concerns, including substance use, will become increasingly prominent. Findings from the 2001 National Household Survey on Drug Abuse indicate that individuals ages 16 to 25 are the most likely age group to use illicit drugs. Many past studies have documented a clear link between youth substance use and the transition from school to the labor force.

Please see the YIW tools entitled "Annotated Reference List" and "Contextual and Other Factors Related to YIW."

13. Can the study population include youth older than 24?

Yes, if they were between the ages of 16 and 24 at the onset of the intervention period.

14. What is the period of YIW support?

Support may be requested for a period of up to 2 years. Subsequent awards for support for up to 3 additional years will be made subject to continued availability of funds and progress achieved.

PROGRAM CONTENT AND METHODS

15. How much detail about the prevention/early intervention programs or interventions to be studied must YIW applicants provide?

Applicants must provide a clear conceptualization of the prevention/early intervention program or intervention and describe the program components and rationale, the process by which the program is intended to work, and the expected outcomes of the program. To the extent possible, descriptions should present programs in the form of a logic model* and include the following:

- Program's goals;
- Available resources for supporting the program during the study period and beyond;
- Target populations or people who are affected by the program;
- Program components or key activities that comprise the prevention/early intervention program. Each component should be clearly distinguishable and measurable (e.g., level or amount of exposure, number of products distributed, number of persons served);
- Mechanisms used to deliver the program components (e.g., worksite health and wellness staff, employee assistance program [EAP] providers, human resources [HR] professionals, counseling professionals, research staff, community providers);
- Program outputs or products that result from the program (e.g., pamphlets and other written materials distributed at the workplace, video or other electronic media available through the workplace, counseling hours provided by the EAP, seminar or workshop presentation materials);
- Intended intermediate and long-term outcomes of the program (e.g., changes in perceptions and/or behaviors, changes in workplace activities or outcomes);
- Antecedent variables or known factors outside of the program that might affect the outputs of the program or put the program success at risk (e.g., changes in contractual relationships with program providers, significant changes in number of employees at intervention or comparison sites); and
- Intervening or known rival events outside of the program that might affect the hypothesized short-term and long-term outcomes of the program (e.g., changes in substance abuse policies, introduction of other related programs).

To the extent possible, applicants also should describe the theoretical underpinnings of the prevention/early intervention program and provide evidence of its utility for similar populations.

**Please see Karuntzos, G.T. "The Logic Model." In The Sage Encyclopedia of Social Science Research Methods (Vol. 3), M.S. Lewis-Beck, A. Bryman, and T.F. Liao, eds., pp. 484-485. Thousand Oaks, CA: Sage.*

16. What requirements are expected of the applicants related to the YIW workplace survey?

Applicants must describe the ability to

- secure approval from the worksite to administer a web-based survey hosted by the cross-site evaluation contractor, which will comply with Government Performance and Results Act (GPRA), Office of Management and Budget (OMB), and CSAP Core Measures Initiative (CMI) data collection requirements;
- communicate the purpose and intent of the survey to the target population and, if required, obtain employee consent to participate; and
- secure an acceptable response rate to meet GPRA and OMB requirements.

17. What are GPRA, OMB, and CSAP CMI requirements?

GPRA. The Government Performance and Results Act of 1993 (GPRA) was enacted by Congress to promote a new focus on improving program performance and to provide greater accountability for results within the federal government. The legislation aimed to accomplish these goals by requiring agencies to develop specific, measurable goals for all federal programs and to report actual results. The GPRA results will be measured through administrative records, process study documentation, and the YIW cross-site survey findings.

OMB. On May 22, 1995, the President signed the *Paperwork Reduction Act of 1995* (PRA), P.L. 10413, into law. The PRA gives specific responsibilities to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). These responsibilities include ensuring that effective and efficient information resource management practices are implemented across the government; the paperwork burden imposed by the federal government on the public is minimized; and the greatest possible public benefit comes from the collection, use, and dissemination of information collected from the public.

CSAP Core Measures Initiative (CMI). The CSAP Data Coordinating Center (DCC) has undertaken the task of developing a set of recommended measures that are appropriate for assessing the risks, resiliency, and substance use of young adults (18 to 25 years of age). The YIW cross-site survey will incorporate appropriate CSAP CMI measures as required.

18. What GPRA measures will be included on the YIW survey?

GPRA questions on the Phase I baseline and Phase II follow-up surveys will include

- basic demographic measures such as age, gender, and race/ethnicity;
- job-related measures, such as job tenure, union status, job type, and occupational title;
- health insurance;
- awareness and use of workplace-based prevention programs;
- substance use measures, such as drinking experience, drug use experience, and perceptions of risk of alcohol and drug use; and
- workplace outcomes, such as injuries, accidents, absenteeism, and workplace theft.

Phase I baseline data collection will inform Phase II GPRA results.

19. What type of study design can be used?

Applicants must propose their own specific individual study design as part of their application. Both experimental and quasi-experimental designs are acceptable, but grantees proposing quasi-experimental designs must demonstrate the comparability of the intervention and comparison groups. All grantees will collect, analyze, and compare prospective data for an intervention group and at least one selected comparison or control group. The intervention and comparison groups should be of approximately equal size. The unit of assignment can be employees or clusters of employees, such as departments, workgroups, or worksites. If employees are not the unit of assignment, applicants should ensure that enough units (e.g., worksites) are assigned to each study condition to allow for meaningful statistical inference. If data are available, grantees will analyze retrospective data to assess longitudinal effectiveness. Programs will evaluate their operational processes and outcomes, participate in a cross-site evaluation study, and develop a replication manual.

Please see the YIW tools entitled "Analyzing Data from Nonrandomized Group Studies," "Propensity Analysis," and "Statistical Power: A Primer."

20. What is the difference between a process evaluation and an outcome evaluation?

A process evaluation documents what services were provided, who delivered them, how they were delivered, and to whom they were provided. An outcome evaluation examines the effect of your project on recipients as well as the factors that contributed to the effects.

21. What is the YIW Process Evaluation?

The process evaluation focuses on describing the details of the sites' interventions and their underlying logic and on providing quantitative information related to intervention "dose" (i.e., how much and what kind of intervention did participants in the intervention and comparison groups actually receive?). Each grantee will be responsible for documenting the implementation of its intervention(s) to support a comprehensive process evaluation.

One important reason for including a thorough process evaluation as part of a comprehensive evaluation strategy is the critical role of process evaluation in establishing the overall evaluation's validity and consequently in interpreting its findings. Inclusion of process evaluation helps guard against falsely concluding that an intervention is not effective, when in fact the intervention was not fully implemented. Process evaluation questions build on the description of the program content documented in Question 15 above and will include the following:

- What are the interventions being tested?
- What is their underlying theory and logic (i.e., how are they *supposed* to work)?
- How were they implemented?
- What is the context in which they were implemented, and did the context change in any meaningful ways over the course of the study?
- What lessons were learned in implementing the interventions that would be helpful to others trying to implement workplace prevention programs?
- To what extent did study participants actually receive an intervention?
- Was it the type and amount of intervention intended by the design?
- What, if any, interventions unintended by the design did participants also receive?
- What changes occurred in participants' cognitions or behaviors during the study period that may *mediate* the interventions' intended outcomes?

22. What type of comparison group can be selected?

Any comparable group of employees who are or would be eligible for the intervention but who do not receive it (or who receive the intervention at a later date than the intervention group) can serve as the comparison group. The comparison group or groups must use the same unit of assignment as the intervention group. That is, if the intervention is a worksite-level intervention, then the comparison group must be comprised of worksites. The comparison group should be matched to the intervention group on all salient characteristics. For employee-level assignment, these include race/ethnicity, age, gender, educational attainment, and occupation, among others. For worksite-level assignment,

salient characteristics include number of employees, level of union activity, industry, and urban/rural status, among others. If matching is not possible or practical, applicants should demonstrate the ability to collect data on all salient characteristics sufficient to allow for statistical control of those characteristics.

Please see the YIW tools entitled "Analyzing Data from Nonrandomized Group Studies," "Propensity Analysis," and "Statistical Power: A Primer."

23. What are "administrative data?"

"Administrative data" refers to any data collected or maintained by or on behalf of the partnering worksite as part of its normal business operations. These include human resource data, such as salaries, absenteeism, or performance reviews; Occupational Safety and Health Administration (OSHA) reporting data on workplace accidents and injuries; workers' compensation claims data; and health care claims or encounters data. Because administrative data are collected for billing, tax, or other business-related purposes, they often pose special challenges when used for research. Applicants should demonstrate knowledge of these challenges as they relate specifically to their proposed administrative data.

Ownership of administrative data is sometimes complicated by contractual arrangements with third-party collection or administrative contractors and by employee confidentiality concerns. Applicants should provide evidence that they can reasonably expect to obtain the administrative data required by their study design. Such evidence may include, but is not limited to, letters of intent from workplace or other relevant representatives; price quotes from data vendors; a summary of the legal justification for obtaining employee-identifiable data without informed consent (all such justifications must be reviewed by an Institutional Review Board for the protection of human subjects before data collection can begin); or draft security protocols, including proposed informed consent forms and processes for obtaining informed consent.

Please see the YIW tools entitled "An Interview Guide for Employee Assistance Program Data Systems," "An Interview Guide for Human Resources Data Systems," and "An Interview Guide for Managed Care Organization Data Systems."

24. What is cost-effectiveness analysis?

Cost-effectiveness analysis (CEA) compares the incremental costs of an intervention or program to the incremental benefits of that intervention or program measured in natural units (e.g., days absent). Because a cost-effectiveness (CE) ratio is always computed relative to some baseline, CEA can be used to rank competing interventions but does not provide information on whether or not the costs of an intervention outweigh its benefits. For example, if a new EAP intervention designed to reduce absenteeism costs $500 more per year than regular EAP services to implement and saves an extra 5 days of absenteeism per year, then that program has a CE ratio of 500/5 = 100 compared to baseline EAP services. In this example, a CE ratio of 100 means that the intervention

cost $100 more per day of absenteeism avoided. If a second intervention to reduce absenteeism had a CE ratio of 50, then that intervention would be preferred to the first because it only costs $50 extra for every day of absenteeism saved. One shortcoming of CEA is that it only examines one outcome at a time and therefore cannot be used to compare interventions that affect different outcomes.

Please see the YIW tools entitled "A Resource Guide to Costing Workplace Programs," "Bray et al., 1996," "French et al., 1995," and "Zarkin et al., 2003."

25. What is cost-benefit analysis?

Cost-benefit analysis (CBA) compares the dollar value of an intervention's outcomes to its costs to derive the net benefits of an intervention. By valuing both the benefits and the costs of an intervention in monetary units, CBA allows the researcher to make statements about whether or not a particular intervention should be done. For example, if an EAP intervention to reduce absenteeism saves $1,000 per year in absenteeism costs and costs $500 per year to implement, then the net benefits of that intervention are $1,000 – $500 = $500. In this case, the intervention saves the company $500 per year and should be implemented. CBA can be used to rank interventions that affect different outcomes because it values all outcomes in dollar units. In general, the intervention with the largest net benefits is the most favored intervention. A major drawback of CBA is that often strong assumptions must be made to value outcomes in dollars, if they can be valued in dollars at all.

Please see the YIW tools entitled "A Resource Guide to Costing Workplace Programs," "Bray et al., 1996," "French et al., 1995," and "Zarkin et al., 2003."

26. What is cost-offset analysis?

"Cost offset" refers to one of the hypothesized benefits of substance abuse treatment. Under the cost-offset hypothesis, treating substance abuse will lower the *overall* health care costs of the substance abuser to the point that the employer or managed care organization (MCO) actually saves money in the long run. For the employer or MCO to save money by treating a substance abuser, the total post-treatment health care expenditures of the substance abuser must fall below pre-treatment expenditures and stay below pre-treatment expenditures long enough to recoup the cost of treatment itself. Researchers should be careful when hypothesizing a cost-offset effect because it may suggest that if no cost offset is found, then employers and MCOs should not invest in the ethically and morally necessary treatment of substance abusers. Furthermore, it is not clear from the scientific literature that researchers should expect a cost offset in all cases, especially in the case of preventative services.

Please see the YIW tools entitled "A Resource Guide to Costing Workplace Programs," "Bray et al., 1996," "French et al., 1995," and "Zarkin et al., 2003."

PARTICIPANT PROTECTION

27. What requirements for data confidentiality and IRB approval will be expected?

Because archival human resource and health claims data are likely to play a major role in the YIW core measures, Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPAA) issues will need to be addressed by each of the grantees. Each of the grantees will need to secure IRB approval for their respective grants and submit to the YIW Cross-Site Evaluation Contractor's IRB a written human subjects protocol that summarizes the approaches and measures that will be taken to ensure the protection and confidentiality of all human subjects data collected as part of the YIW cross-site evaluation. Per federal guidelines (42 CFR Part 2), the Cross-Site Evaluation Contractor will in turn be responsible for assuring that all data submitted as part of the YIW initiative are either non-identifiable or appropriately protected before IRB approval is obtained for the cross-site evaluation. To address IRB and HIPAA-related concerns among the grantees and their partnering organizations, the Cross-Site Evaluation Contractor will provide IRB and HIPAA-related technical assistance. For grantees who are not affiliated with a research organization or do not have access to a local IRB, the Cross-Site Evaluation Contractor's IRB can serve as the primary IRB for the individual grantee submission. These arrangements can be made upon request.

As part of the data procurement process, the grantees may need to educate and negotiate with their collaborating organizations to obtain protected data. In most cases, HR departments and health plans will have procedures in place for complying with HIPAA in their everyday operations, but they may not be familiar with the provisions under HIPAA for how they can use or disclose health information about their employees for research purposes. Grantees will need to educate their partners on procedures they can follow (e.g., prepare a limited data set with the necessary identifiers removed from the data) in order to comply with HIPAA and share their data.

As an added measure of security, each grantee may also choose to apply for a certificate of confidentiality from CSAP. This certificate provides additional (but not exhaustive) assurance that data obtained from the collaborating worksites and individual human subjects will not be shared outside of the research team and will remain confidential at all times throughout the course of (and beyond) the study period. The Cross-Site Evaluation Contractor can provide technical assistance upon request to educate the grantee on the application process.

Finally, as part of the cross-site evaluation requirements, each of the grantees will be required to submit core measures directly to the Cross-Site Evaluation Contractor. Although non-identifiable data will be preferred for the cross-site evaluation, partnering organizations still may be concerned about confidentiality. If so, the grantees may need to provide further assurance to the partnering organizations that the Cross-Site Evaluation Contractor will securely maintain the data and, upon request, protect the identity of the partnering organization. The Cross-Site Evaluation Contractor will support all requests for written assurance and when additional assurance is required will encourage and support

the local grantee in applying for a certificate of confidentiality naming the Cross-Site Evaluation Contractor as a research partner, thus covering the cross-site data under the local certificate. The level of technical assistance required by each of the grantees will vary based on previous research experience, the sensitive nature of the interventions, and the requirements for confidentiality from the partnering organizations.

Please see the YIW tools entitled "An Interview Guide for Employee Assistance Program Data Systems," "An Interview Guide for Human Resources Data Systems," and "An Interview Guide for Managed Care Organization Data Systems."

REPLICATION MANUALS

28. Why does SAMHSA/CSAP want replication manuals produced at the end of the program?

SAMHSA/CSAP plans to disseminate findings and replication materials of successful programs to those desiring to build or revise their own programs.

Phase II grantees completing the 5-year process will have sufficient documentation to apply for National Registry of Effective Programs (NREP) status.

Please see the YIW tools entitled "A Guide to the NREP Review Process" and "NREP Program Descriptions."

29. What are the requirements for the replication manuals?

Replication training manuals, at a minimum, must have a detailed description of the following:

- The YIW model(s); workplace(s); employees, their families, and communities; covered lives; substance abuse prevention/early intervention services covered and provided; cross-system and provider relationships; and a general description of employees' substance abuse knowledge, attitudes, and behavior;
- Population characteristics: gender, culture, race, ethnicity, age, educational achievement, and linguistic background;
- Initiation and implementation processes and procedures including organizational issues, staff, system access, and utilization rates;
- Data collection methodologies and instruments, measures, and analysis used to determine effectiveness;
- Data storage and handling, including security and privacy issues, and management information system issues; and
- Outcomes.

SAMHSA/CSAP encourages applicants to include cost-effectiveness information in their replication training manuals.